

US EPA ARCHIVE DOCUMENT

DATE OUT: March 27, 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: **Manufacturing Use Product [],**
End Use Product [X]

BARCODE No.: D289002 EPA RECEIVED DATE: 02/13/03

EPA Reg. No.: 100-987 PRODUCT NAME: Brodifacoum Technical

MRIDs: 458594-01

COMPANY NAME: Syngenta Crop Protection, Inc.

Action Code: 674

FROM: Bentley C. Gregg, Ph.D., Product Chemist
Product Chemistry Team
PRB/SRRD (7508C)

Bentley C. Gregg
3/27/03

TO: Venus Eagle-Kunst, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

The registrant, Syngenta Crop Protection, Inc., submitted a revised Confidential Statement of Formula (CSF; dated 11 Feb. 2003) and a Product Chemistry study report (MRID 458594-01) containing information regarding Guideline 830.1600, in support of a request for FIFRA Section 4 reregistration of their end use product, **Brodifacoum Technical**, EPA Reg. No. 100-987.

A Reregistration Eligibility Decision (RED), Case # 2755, was issued in August 1998 for the Technical Grade Active Ingredient (TGAI), Brodifacoum, which has the chemical name: 3-(3-(4'-Bromo-(1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl)-4-hydroxycoumarin. The RED indicated that the generic data concerning the physical/chemical properties of the active ingredient, brodifacoum, were acceptable, but that additional data were required for the specific products, including a revised CSF, a revised product label, and additional data regarding the product chemistry (such as production methods, analytical procedures, and physical and chemical properties data). The registrant has submitted various information since the RED was issued, and the Agency has evaluated and accepted these data in Product Chemistry reviews by Paul Horng, dated 6/MAR/02 and 14/JAN/2003. Based on the information presented in these Product Chemistry reviews, it was concluded that the registrant still had a requirement to submit acceptable data for Guideline 830-1600, Description of Materials Used to Produce the Product, as well as an acceptable CSF and a revised label with a corrected percent nominal concentration.

FINDINGS:

1. Except for providing the information concerning the Description of Materials Used to Produce the Product, an acceptable CSF, a revised label, and certain other newly identified data gaps, this Product Chemistry review concludes that most of the physical and chemical property data previously submitted are adequate, and support the reregistration requirements for the end use product, Brodifacoum Technical (EPA Reg. No. 100-987).
2. The registrant has submitted a study report (MRID 458594-01) which provides

information which fulfills the data requirements under Guideline 830-1600, Description of Materials Used to Produce the Product. However, based on information described in Confidential Appendix A, this review now finds the information available to be insufficient concerning how these materials are in fact used; thus, additional information must be cited or submitted to address Guideline 830-1620, Discussion of Production Process, including adherence to Good Manufacturing Practices, as well as to clarify the information previously submitted concerning Guideline 830-1670, Discussion of Formation of Impurities, for the subject technical grade active ingredient (TGAI) product.

3. Concerning the revised CSF (a Basic formulation, dated 11 Feb. 2003), this review has identified problems regarding the Upper Certified Limit of [REDACTED] for the active ingredient and the Lower Certified Limit of [REDACTED] for the combined Process Related Impurities (see Confidential Appendix A for additional details). In addition, the CSF lists Upper Certified Limits for each Process Related Impurity which differ substantially from the values calculated by this reviewer, as per the regulations of 40 CFR 158.175 (b)(2) (see Confidential Appendix A for additional details concerning these Certified Limits.)
4. Various other aspects of the CSF are acceptable for reregistration, including especially the data reported in Blocks 7, 8, and 9.
5. Regarding the label submitted in January 2003, the nominal concentrations of the active ingredient (Brodifacoum Technical) and the Inert Ingredients are 90% and 10%, respectively. However, based on the CSF and the Product Chemistry review (dated 14/JAN/2003), the registrant has provided information in various sources which reported that the active ingredient is present at a nominal concentration of 95% and the inert ingredients at 5%. The registrant has not yet submitted a revised label to correct this deficiency.
6. The Product Chemistry review (dated 14/JAN/2003) indicated that the Storage and Disposal statement on the submitted product label should delete the sentence "Do not reuse empty container" and that the entire Storage and Disposal statement should be placed in a box, but these deficiencies have also not yet been addressed. This review also requests that the registrant clarify whether packaging for the Technical product is in both metal containers and plastic bags, as indicated in the Storage and Disposal Statement.

CONCLUSIONS:

Other than submitting or citing additional information to address Guideline 830-1620, Discussion of Production Process (as well as additional details concerning GMP aspects of the production process requested in Confidential Appendix A) and to clarify previously submitted information for Guideline 830-1670, Discussion of Formation of Impurities (Finding 2), and a revised CSF with various corrections to the certified limits (Finding 3), as well as a revised label with the corrected information for the nominal concentrations of the active ingredient and inert ingredients (Finding 5) and the Storage and Disposal Statement, including the types of packaging (Finding 6), the registrant has satisfied the product chemistry requirements for reregistration of the end use product, **Brodifacoum Technical**, Reg. No. 100-987.

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BRODIFACON

Page _____ is not included in this copy.

Pages 3 through 5 are not included in this copy.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
- _____ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- ☒ Description of quality control procedures.
- _____ Identity of the source of product ingredients.
- _____ Sales or other commercial/financial information.
- _____ A draft product label.
- _____ The product confidential statement of formula.
- _____ Information about a pending registration action.
- _____ FIFRA registration data.
- _____ The document is a duplicate of page(s) _____.
- _____ The document is not responsive to the request.
- _____ Internal deliberative information.
- _____ Attorney-Client work product.
- _____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
